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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,702	06/13/2001	Katherine A. High	0800-0024	5537

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/880,702	HIGH, KATHERINE A.	
	Examin r	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sh et with th correspond nce address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-14 and 16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 6-14,and 16-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ *are subject to restriction and/or election requirement.*

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/31/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Non-Final Rejection

Claims 1, 2, 6-14, and 16-26 are pending examination.

Applicant's traversal, the sequence listing, the amendment to claims 1, 6, 7, 13, and 16-18, the cancellation of claims 4, 5, and 15 filed on 10/31/03 are acknowledged and considered.

Drawings

The drawings were received on 10/31/03. These drawings are acceptable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Russell et al., (US 6,156,303) as evident by Couto et al. (US Patent 6,200,560).

Russell teaches a method of administering rAAV (AAV3B or AAV6) into an individual systemic or locally a human Factor IX and expressing the Factor IX in

hepatocyte cells of the individual (column 26, lines 13-25 and lines 59-65). The method can be used to treat a clotting deficiency in a human (column 24, lines 24-63). Russell teaches introducing a heterologous nucleic acid sequence into a liver or a muscle cell *in vivo* (column 72). Administering the rAAV to the muscle of a human would result in the rAAV being injected into fast and slow twitch muscle fibers of the muscle. Furthermore, Russell teaches that as many as 85% of the normal human population has antibodies against various AAV types, particularly AAV2 (column 2, lines 1-6). Thus, the method taught by Russell would anticipate delivering Factor IX to a human with AAV-2 antibodies since the vast majority of humans would be expected to be AAV-2 seropositive.

Couto teaches that hemophilia is a clotting deficiency. Thus, the method taught by Russell would anticipate using rAAV to delivery Factor IX to treat hemophilia in a human since hemophilia is a clotting deficiency.

Claims 1, 2, 11, 12, 13, 14, 16, 17, 18, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Samulski et al., (US 6,670,176 B1) as evident by Couto et al. (US Patent 6,200,560).

Samulski teaches a method of treating hemophilia in a human comprising administering to the liver of a human a rAAV comprising a nucleotide sequence encoding a Factor IX protein (column 6, lines 1-10 and column 14, lines 13-40). Administering the rAAV to the liver of a human would result in the Factor IX being secreted into an extracellular space and blood vessels of the human.

Couto teaches that 85% of the human population is seropositive for AAV-2 serotype (column 12). Thus, the method taught by Samulski would anticipate delivering Factor IX to a human with AAV-2 antibodies since the vast majority of humans would be expected to be AAV-2 seropositive.

Claims 1, 2, 6, 7, 8, 9, 10, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 and 26 remain rejected under 35 U.S.C. 102(e) as being anticipated by High et al. (IDS, US Patent 6,093,392 as evident by Couto et al. (US Patent 6,200,560).

High teaches a method of treating hemophilia in a human comprising: a) providing a recombinant adeno-associated virus vector (rAAV), said rAAV comprising a nucleic acid encoding human Factor IX operably linked to an expression control; and b) administering an amount of said rAAV to a mammal wherein said Factor IX is expressed at levels having a therapeutic effect on said human and wherein said therapeutic effect is an increase in coagulation of blood (column 29). High teaches administering the rAAV to the muscle tissue of the human (column 30). Administering the rAAV to the muscle of a human would result in the rAAV being injected into fast and slow twitch muscle fibers of the muscle.

Couto teaches that 85% of the human population is seropositive for AAV-2 serotype (column 12). Thus, the method taught by High would anticipate delivering Factor IX to a human with AAV-2 antibodies since the vast majority of humans would be expected to be AAV-2 seropositive.

The 102(e) reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention. An affidavit or

declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2306. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the patent may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

Applicant's arguments filed 10/31/03 have been fully considered but they are not persuasive for the following reasons:

The Declaration filed on 10/31/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the 102(e) reference for the reasons set forth above. See MPEP 2306.

The subject matter used in the rejection is claimed subject matter and not unclaimed subject matter as stated by Dr. High. See claims 3 and 8. Couto teaches that 85% of the human population is seropositive for AAV-2 serotype (column 12). Thus, it would be inherent that the method claimed by High and Herzog embraces delivering Factor IX to a human with AAV-2 antibodies since the vast majority of humans would be expected to be AAV-2 seropositive.

Furthermore, the Declaration filed on 10/31/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the 102(e) reference because Dr. High does state what is the unclaimed subject matter invented solely by Dr. High and not Dr. Herzog and Dr. High.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 6, 7, 8, 9, 10, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 8 of U.S. Patent No. 6,093,392 in view of Couto et al. (US Patent 6,200,560).

The claims of patent '392 are drawn to a method of treating hemophilia in a human comprising: a) providing a recombinant adeno-associated virus vector (rAAV), said rAAV comprising a nucleic acid encoding human Factor IX operably linked to an expression control; and b) administering an amount of said rAAV to a mammal wherein

said Factor IX is expressed at levels having a therapeutic effect on said human and wherein said therapeutic effect is an increase in coagulation of blood.

The difference between the claims of the instant application and patent '392 is that the instant application teaches that humans have anti-AAV antibodies and the patent '392 does not teach that the majority of humans have anti-AAV antibodies.

However, Couto teaches that 85% of the human population is seropositive for AAV-2 serotype (column 12). Thus, the method taught by High would be unpatentable over claims 3 and 8 of High in view of Couto '560 since the humans in the method of High and Couto would be expected to be AAV-2 seropositive. Therefore, the claims of the instant application and patent '392 in view of Couto are obvious variants of one another.

Claim 1, 2, 6, 7, 8, 9, 10, 13, 14, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25 and 26 directed to an invention not patentably distinct from claims 3 and 8 of commonly assigned patent 6,093,392. Specifically, the claims of patent '392 are drawn to a method of treating hemophilia in a human comprising: a) providing a recombinant adeno-associated virus vector (rAAV), said rAAV comprising a nucleic acid encoding human Factor IX operably linked to an expression control; and b) administering an amount of said rAAV to a mammal wherein said Factor IX is expressed at levels having a therapeutic effect on said human and wherein said therapeutic effect is an increase in coagulation of blood.

The difference between the claims of the instant application and patent '392 is that the instant application teaches that humans have anti-AAV antibodies and the patent does not teach that the majority of humans have anti-AAV antibodies.

However, Couto teaches that 85% of the human population is seropositive for AAV-2 serotype (column 12). Thus, the method taught by High would be unpatentable over claims 3 and 8 of High in view of Couto '560 since the humans in the method of High and Couto would be expected to be AAV-2 seropositive. Therefore, the claims of the instant application and patent '392 in view of Couto are obvious variants of one another.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon

the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Response to Arguments

Applicant's arguments, see paper no., filed 10/31/03, with respect to 102(a) over Kay (Nat Genetics) and Couto (US 6,200,560) references have been fully considered and are persuasive. The rejection of claims 1, 2, 4-10, and 13-26 has been withdrawn because of the Declaration, pursuant to *In re Katz* under of Dr. Katherine High and the cancellation of claims 4, 5, and 15. The Declaration filed on 10/31/03 under 37 CFR 1.131 is sufficient to overcome the 102(a) reference. See pages 6 and 7.

Applicant's arguments, see paper no., filed 10/31/03, with respect to 102(e) over Couto (US 6,200,560) references have been fully considered and are persuasive. The rejection of claims 1, 2, 4, 8-14, 21, and 24 has been withdrawn because of the insertion of claims 5 and 15 into claims 1 and 13, respectively. See page 7.

Applicant's arguments, see paper no., filed 10/31/03, with respect to 103(a) over Kay in view of Couto have been fully considered and are persuasive. The rejection of claims 1, 11, and 12 has been withdrawn because of the Declaration, pursuant to *In re Katz* under of Dr. High. See page 7.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-

0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE - Art Unit 1635, can be reached at (703) 306-3217.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER

Brian Whiteman
Patent Examiner, Group 1635